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Filed : November 10, 1999

REMARKS

With this response, Claims 3-39, and 47-57 are pending in the present application. By way of the present amendment, Applicant amended Claims 50 and 56 to more fully define over the prior art of record.

Claim rejections - under 35 U.S.C. § 103(a) over Auth – Claims 50-51

Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auth et al. Independent Claim 50 has been amended to more fully define over Auth.

Discussion of Auth and Claims 50-51

Auth discloses a percutaneous aspiration thrombectomy catheter that provides aspiration to aspirate or secure the thrombus and to capture emboli created during the procedure. Auth teaches using a pump to apply a vacuum to an aspiration catheter to make “it easy to advance the catheter tip through the thrombus with a steady vacuum pressure.” Col. 4, lines 47-49. After the aspiration catheter is removed, “another rapid exchange catheter can be advanced over the guidewire.” Col. 6, lines 5-6. Auth introduces the problem that during a thrombectomy procedure, a “serious possible disadvantage is that fragments of the clot may embolized downstream.” Col. 2, lines 19-20. To this end, Auth introduces an aspiration catheter “for providing vacuum down the catheter lumen to the distal tip, for drawing thrombus into the lumen.” Col. 4, lines 21-22.

Auth teaches that an aspiration catheter is used to draw thrombus into the lumen and there is no teaching or suggestion to use additional protection. Amended claim 50 now recites, *inter alia*, “activating an occlusive device within said vessel to at least partially occlude blood flow.” Applicant respectfully submits that Claim 50 is allowable over Auth.

Furthermore, there is no motivation to combine Auth with a reference showing occlusive protection. In fact, one of the objects of Auth’s invention is to minimize fragmentation of clots. Col. 2, line 24. Nowhere does Auth appreciate the benefits of using occlusive protection as described in certain embodiments of the present application. Therefore, Applicant respectfully submits that Claim 50, as amended, is patentable over the prior art of record and also recites a unique combination of features not taught or suggested by the prior art.

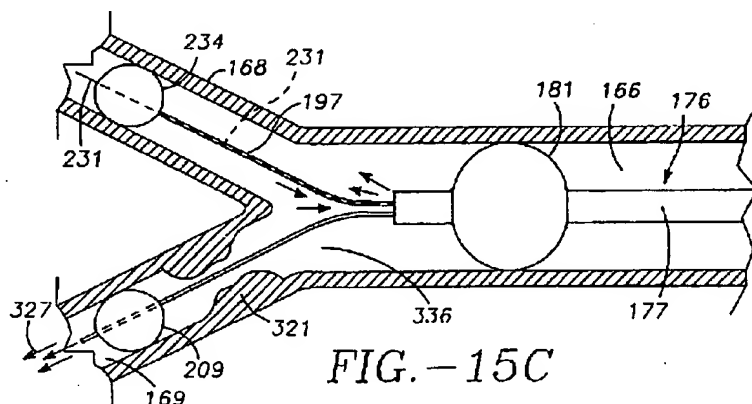
Claim 51 is patentable for at least the same reasons Claim 50 is patentable and also recites a unique combination of features not taught or suggested by the prior art. Accordingly, Applicant submits that Claim 51 is also in condition for allowance.

Claim rejections - under 35 U.S.C. § 103(a) over Auth in view of Imran – Claims 21, 23-28, 48-49, and 54-57

Claims 21, 23-28, 48-49, and 54-57 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Auth et al. in view of Imran. The following discussion regarding these claims will be segmented and the claims grouped by independent claim along with the corresponding dependent claims.

Discussion of Imran

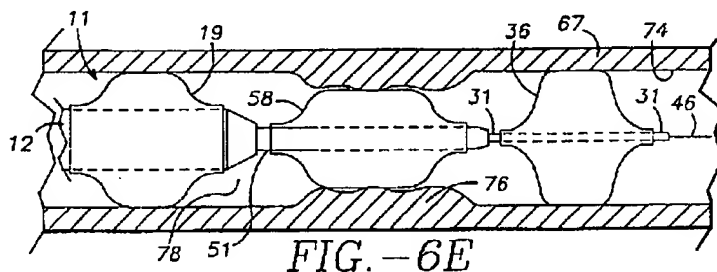
Imran ('650) teaches in one embodiment a catheter apparatus and method for treating occluded vessels in which a standard guidewire is introduced until it is near the aorta arch. Col. 12, lines 10-15. With reference to Figure 15C, reproduced below for convenience, a proximal occlusion balloon 176 catheter is advanced until its distal extremity enters the common carotid and is near the bifurcation. *Id.* at 15-20. The proximal balloon 181 is inflated and a roller pump provides a negative pressure through the proximal balloon catheter to establish retrograde blood flow. *Id.* at 20-31. A perfusion balloon catheter 193 is advanced into the internal carotid past the stenosis, and the perfusion balloon is inflated. *Id.* at 58-61. A balloon-on-a-wire catheter 197 is then advanced into the external carotid artery and the balloon is inflated to occlude the external carotid. *Id.* at 63 et seq. The lesion is now bracketed by the proximal balloon, perfusion balloon and the balloon-on-a-wire and appropriate therapy is performed on the stenosis or lesion. Col. 13, lines 33-36.



Imran has no teaching or suggestion for crossing the lesion with the proximal balloon catheter, especially in view of the fact that a proximal balloon has been placed and inflated proximal the occlusion. Imran specifically mentions that a guidewire can be used to aide in advancing the perfusion balloon catheter; therefore, the perfusion balloon catheter is not a

guidewire. Accordingly, this embodiment of Imran has no teaching or suggestion of a guidewire with an occlusive device distal to an occlusion.

In an additional embodiment, Imran teaches an apparatus and method for treating occluded vessels that are not bifurcated, such as a saphenous graft or in one of the right or left carotid arteries. Col. 5, lines 1-5. The apparatus and method are described in relation to Figures 6A - 6E, a copy of Figure 6E is reproduced below for convenience. A guiding catheter is positioned proximal to an occlusion and a proximal balloon 19 on a catheter assembly 11 is inflated to occlude the vessel. *Id.* at 28-37. A negative pressure is applied distal to balloon 19 to aspirate blood and a guide wire 46 is advanced across the occlusion. *Id.* at 37-46. A second balloon catheter 31 is introduced through the guiding catheter until the second balloon 36 is distal of the stenosis 76, after which the second balloon 36 is inflated. *Id.* at 64 et seq. "As soon as the second balloon 36 has been inflated, it can be seen that there is provided a working space 78 between the first and second balloons 19 and 36.



Imran does not teach that the aspiration catheter, which in this embodiment is the catheter carrying balloon 19, ever crosses the occlusion. To the contrary, the aspiration catheter includes a proximal occlusion balloon, which prevents the aspiration catheter from crossing the occlusion. While Imran teaches a second elongate flexible tubular member 31 with a second balloon 36 thereon, there is no motivation to use this second balloon in a method in which the aspiration catheter crosses the occlusion.

Claims 21, 23-28, and 30.

Independent Claim 21 is not made obvious by the combination of Auth and Imran. Specifically, there is no motivation or suggestion to combine Auth and Imran. Imran does not teach or suggest crossing an occlusion with an aspiration catheter because Imran teaches an aspiration catheter having a proximal occlusion balloon, which makes crossing the occlusion with the aspiration catheter difficult, if not impossible. Furthermore, either alone or in

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combination with Imran, Auth does not suggest using a guidewire having an occlusive device on its distal end because Auth does not view distal protection as necessary in view of the blood flow created by the aspiration catheter.

Furthermore, to the extent a guidewire with an occlusive device is disclosed by Imran, there is no teaching or suggestion that such a guidewire could be used in connection with the aspiration methods disclosed by Auth. This is especially true because the devices described by Imran are intended primarily for methods in which aspiration occurs through a stationary catheter with an inflated proximal balloon, and not for methods such as described in Auth. The Examiner's suggested combination of these references is therefore contrary to the teaching of the references individually.

Accordingly, the teachings of Auth and Imran are contrary to at least Claim 21 which recites, *inter alia*, "delivering a guidewire having an occlusive device at its distal end until the distal end is distal said occlusion; delivering an aspiration catheter until its distal end is proximal to the occlusion; activating said occlusive device; and crossing the site of the occlusion with the distal end of the aspiration catheter while aspirating."

In addition, the claims that depend from Claim 21 recite additional unique combinations of features not made obvious by the prior art references. For example, Claim 25 claims, *inter alia*, "introducing said aspiration catheter after performing therapy to remove debris generated during said therapy." Neither Auth nor Imran teach the reintroduction of the aspiration catheter following treatment.

Accordingly, Applicant respectfully submits that Claims 21, 23-28, and 30 are not obvious in light of the prior art references, either individually or in combination, and requests allowance of the same.

Claims 48-49

As discussed above, there is no motivation to combine Auth and Imran. Moreover, even if the references were combined, it would not result in the embodiments claimed in Claims 48-49. For example, claim 48 recites, *inter alia*, "exchanging the guidewire for a guidewire having an occlusive device on its distal end." Neither reference teaches or suggests at least this limitation and the combination of the two would likewise not teach at least this limitation. In light of the foregoing, Applicant respectfully requests withdrawal of the rejection and allowance of Claims 48-49.

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Claims 54-56

Claims 54-56 depend from Claim 50, and therefore, Claims 54-56 are patentable for at least the same reasons as Claim 50. As discussed above in relation to Claims 50-51, Auth alone does not make these claims obvious. Moreover, as discussed elsewhere herein, the addition of Imran does not add an appropriate teaching to Auth to make these claims obvious. Specifically, Claim 54 recites, *inter alia*, "further comprising exchanging the guidewire for a guidewire having an occlusive device on its distal end." Neither of these references teach or suggest at least this limitation of Claim 54.

Claim 57

Claim 57 depends from Claim 21, and as such, is patentable for at least the reasons given above in relation to Claim 21. Claim 57 also recites a unique combination of features not taught or suggested by the prior art.

Allowable Subject Matter

Applicant wishes to thank the Examiner for the indication of allowance regarding Claims 3-13, 14-20, 31-33, 34-39, and 47. Additionally, the Examiner has indicated that Claims 22, 29 and 52-53 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Based upon the above remarks, Applicant respectfully submits that claims 22, 29 and 52-53 are currently in condition for allowance because, in part, their respective base claims and any intervening claims are also in current condition for allowance.

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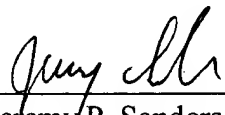
CONCLUSION

Applicant respectfully submits that all the pending claims overcome the prior art of record and are in condition for immediate allowance. Should there be any questions or issues that could be resolved via a telephone conversation, Applicant invites the Examiner to contact the undersigned at the number shown below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 18 March 2003

By: 
Jeremy P. Sanders
Registration No. 47,916
Attorney of Record
2040 Main Street
14th Floor
Irvine, CA 92614
949-760-0404

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